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10/579,966	05/23/2006	Ezio Bombardelli	2503-1217	9265

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EXAMINER

DAVIS, DEBORAH A

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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,966	Applicant(s) BOMBARDELLI, EZIO	
	Examiner Deborah A. Davis	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-25-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species *Hypericum* and *Zanthoxylum* in the reply filed on June 25, 2007 is acknowledged. Claims 15-16 are drawn to non-elected subject matter.

The traversal is on the ground(s) that the species election fails to satisfy the requirement of the PCT rules 13.1 and 13.2. This is not found to be persuasive because in Markush Practice, wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2 and 13.1. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. However, the alternatives *are not similar* in nature. Each plant species in 1(b) and 1(c) are different in composition and structure. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 17 is objected to because of the following informalities: *Zanthoxylum bungeanum* is all one word and should be two. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recite the limitation "wherein Ginkgo biloba terpenes are present in the free form" is vague because it is unclear as to what "free form" means. Also, the limitation "free form" lack antecedent basis.

Claim 4 recite the limitation "Ginkgo biloba terpenes are present in the form of complex with natural or synthetic phospholipids" is vague because it is unclear as to what the limitation "the form of complex" encompasses. Are the Ginkgo biloba terpenes mixed with natural or synthetic phospholipids to form a complex?

Claim 5 recite the limitation "the total triterpenes content ranges from 60 to 100%" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recite the limitation "the total triterpenes content is 90%" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recite the limitation "the bilobalide content ranges from 20 to 70%" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recite the limitation "the bilobalide content is 45%" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recite the limitation "the total A, B, C and J ginkgolides content ranges from 25 to 75%" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recite the limitation "the total A, B, C and J ginkgolides content is 50%" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castelli et al (US 7,008,627) in view of Koch et al (US 7,166,310) and in view of Bombardelli et al (US 6,419,950).

A topical composition for the treatment of atopic dermatitis, skin allergic conditions and acne comprising (a) Ginkgo biloba terpenes; (b) floroglucinols, either pure or in a mixture thereof, extracted from elected species Hypericum sp, and (c) Zanthoxylum bungeanum is apparently claimed.

The reference of Castelli et al beneficially teaches extracts obtained from Ginkgo biloba leaves that contain terpenes. The Ginkgo extracts have excellent anti-inflammatory activity that has been demonstrated on cutaneous cells such as keratinocytes. The extracts are a cosmetic (i.e. atopic) for treating sensitive skin (see column 4, lines 34-67, e.g.).

The reference of Koch et al beneficially teaches topical medicaments comprising extracts of hypericum perforatum having a hyperforin content of at least 2% to 4%.

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According to the instant specification on page 3, hyperforin are floroglucinols. The topical medicament is useful in the treatment of acne, atopic dermatitis and other skin disorders (see abstract, and column 4, lines 37-65, e.g.).

The reference of Bombardelli et al beneficially teaches an extract of the pericarp of *Zanthoxylum bungeanum* for treating burns, itching and in all types of skin treatments requiring local analgesic or anti-itching action (see column 1, lines 45-67 and column 2, lines 1-10, e.g.). The extracts also contain isobutylamide content, as claimed (column 3, lines 39-45, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit and to further use the combined ingredients to treat a patient in need thereof since each is well known in the art for the same purpose (e.g., treating skin conditions) and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The

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adjustment of particular conventional working conditions (i.e. percentage amounts of the instant extracts) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

Claims 1-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being obvious over Castelli et al (US 7,008,627) in view of Koch et al (US 7,166,310) in view of Bombardelli et al (US 6,419,950) in further view of Bombardelli et al (US2006/0275246).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

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application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Castelli et al, in view of Koch et al, in view of Bombardelli et al (US 6,419,950) has been set forth above but does not teach extracts of ferutinine and Ferula.

The reference of Bombardelli et al beneficially teaches that ferutinine and Ferula extracts surprisingly proved able to increase collagen biosynthesis and to give firmness and elasticity to the skin (see paragraph 0022, e.g).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further include ferutinine and ferula taught by Bombardelli into the extracts taught by Castelli et al, Koch and Bombardelli et al based on the beneficial teachings of increasing collagen and elasticity of the skin. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

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Claims 20-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Castelli et al (US 7,008,627) in view of Koch et al (US 7,166,310) in view of Bombardelli et al (US 6,419,950) as applied to claim 1-14, 17 and 22 above, and further in view of Vincene M. Parrinello (US 5,578,312) and Lupulet (Pub#RO108642).

The teaching of Castelli et al, in view of Koch et al, in view of Bombardelli et al (US 6,419,950) has been set forth above, but does not teach lauric acid and Oenothera biennis oil as a lipophilic excipient.

The reference of Vincene M. Parrinello beneficially teaches a skin care system that includes Evening primrose (oenothera biennis) and lauric acids as active ingredients and known for their ability to enhance retention of moisture, vitamins and minerals by the skin (see column 4, lines 1-38, column 9, lines 1-11, e.g.).

The reference of Lupulet et al beneficially teaches a cosmetic day cream comprising Oenothera biennis oil as an active ingredient useful for skin having a predisposition towards acne, eczema and has emollient, moisturizing, nutritive and light protectant effects (see entire abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further include oenothera biennis oil and lauric acid taught Parrinello and Lupulet into the extracts taught by Castelli et al, Koch and Bombardelli et al above based on the beneficial teachings of their ability to retain moisture in the skin, treat acne, eczema and other benefits to the skin recited above. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Patent Examiner
Art Unit 1655
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